



# International Code of Conduct on the Distribution and Use of Pesticides

## Guidelines on Compliance and Enforcement of a Pesticide Regulatory Programme



FOOD AND AGRICULTURE ORGANIZATION  
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## Definitions

For the purposes of these *Guidelines*:

**Administrative action** means an enforcement response such as a sanction or an order that can be issued directly by the administrative authority without the initial involvement of the judiciary.

**Civil judicial action** means an enforcement response such as a sanction or an order that is obtained through the civil court system.

**Compliance** means the full implementation of legal requirements.

**Compliance incentives** means specific rewards or benefits provided in exchange for compliance, especially for voluntary compliance before detections of any violations by government.

**Compliance monitoring** means collecting and analyzing information on compliance status of an entity or facility or of an industry or economic sector.

**Compliance promotion** means any activity that encourages voluntary compliance with requirements. Examples of compliance promotion include educational programmes and technical assistance.

**Civil enforcement** means investigation and legal actions to compel compliance and/or impose sanctions that involve the civil (non-criminal) legal system.

**Criminal enforcement** means investigation and legal actions to compel compliance and/or impose sanctions that involve the criminal justice system.

**Deterrence** means an atmosphere in which people are discouraged from violating requirements and motivated to choose to comply in order to avoid adverse consequences.

**Disposal** means any operation to recycle, neutralize, destruct, isolate or abandon pesticide waste, used containers and contaminated materials.

**Distribution** means the process by which pesticides are supplied through trade channels to local or international markets.

**Enforceable** means able to be enforced.

**Enforcement** means the set of actions that governments or others take to achieve compliance by the regulated community with pesticide regulatory requirements and /or to halt situations that may endanger public health of the environment. Government enforcement usually includes activities like investigations, negotiations and legal actions.

**Environment** means surroundings, including water, air, soil, and their interrelationship as well as all relationships between them and any living organisms.

**Establishment** –see facility.

**Facility** means any place or operation where pesticides are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed or where records relating to such activities are maintained.

**Fine** –see monetary penalty.

**Inspection** means official review and examination of the compliance status of a facility.

**Judicial enforcement** means legal enforcement actions involving the courts and the judiciary.

**Label** and **labeling** mean the written, printed or graphic matter on, or attached to, the pesticide or the immediate container thereof and also to the outside container or wrapper of the retail package of the pesticide. Specific national legislation may define labeling to include additional material.

**Level playing field** means that competitors within the regulated community bear the same burdens and costs of compliance, and that no one gains a competitive advantage from avoiding the costs of compliance.

**Licence** –see registration.

**Manufacturer** means a corporation or other entity in the public or private sector or any individual engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product.

**Marketing** means the overall process of product promotion, including advertising, product public relations and information services as well as the distribution and sale on local or international markets.

**Monetary penalty** means a sanction that is paid in currency.

**Monitoring** means collection and analysis of information on the status of, for example, compliance, environmental conditions, or public health events such as poisoning incidents.

**NGO** means a public interest non-governmental organization that is not directly part of the regulated community.

**Order** means a document backed by the force of law that requires a violator to take certain action within a certain time period to correct a violation, cease illegal activity or remove or reduce an imminent hazard.

**Personal Protective Equipment** means any clothes, materials or devices that is designed to provide protection from pesticide exposure during handling and application, usually for those actively engaged in handling and application.

**Pesticide** means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. National legislation may define pesticide more or less broadly. For purposes of these *Guidelines*, the national legislative definition of pesticide is intended.

**Pesticide industry** means all those organizations and individuals engaged in manufacturing, formulating or marketing pesticides and pesticide products.

**Pesticide legislation** means any laws intended to regulate the manufacture, marketing, distribution, labeling, packaging, use or disposal of pesticides as well as other activities related to pesticides intended by national governments to be included in their pesticide legislation.

**Pesticide product** means the pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.

**Registration** means the process whereby the responsible national government or regional authority approves the sale and use of a pesticide following the evaluation of comprehensive scientific data demonstrating that the product is effective for the intended purposes and does not pose unacceptable risks to human or animal health or the environment. Registration also refers to the licence or authorization to sell a pesticide product following the conclusion of the registration process.

**Regulated community** means those individuals, facilities, businesses, and/or institutions, whether private or public, that are subject to pesticide legislation and implementing regulations, licences, permits, or orders.

**Regulated entities** –see regulated community.

**Regulations** mean the more detailed implementing provisions usually issued by the administrative authorities to describe the specific means by which the regulated community is required to carry out the provisions of legislation.

**Requirements** mean specific practices and procedures established as a legal duty.

**Residue** means any specified substances in or on food, agricultural commodities, animal feed, or environmental media from the use or disposal of a pesticide. The term includes any derivatives of a pesticide such as conversion products, metabolites, reaction products and impurities considered to be of importance.

**Sanctions** mean adverse consequences imposed upon violator(s).

**Self-monitoring** means the process by which a member of the regulated community conducts monitoring relating to its own operations (see definition of monitoring).

**Self-record keeping** means the process by which members of the regulated community maintain their own records of certain regulated activities they perform and/or of their self-monitoring activities.

**Self-reporting** means the process by which members of the regulated community provide government authorities (or, where required, the public) with self-monitoring and/or self-recordkeeping data regularly or upon request.

**Use pattern** means the combination of all factors involved in the use of a pesticide, including the concentration of active ingredients in the preparation being applied, rate of application, time of treatment, number of treatments, use of adjuvants and methods and sites of application which determine the quantity applied, timing of treatment and interval before harvest.

**Violation** means noncompliance with a requirement.

# Guidelines on Compliance and Enforcement of a Pesticide Regulatory Programme

## 1. Introduction

Increasingly, nations on all continents and at all stages of development have adopted systems for the management and regulation of pesticides. Many have relied on the *International Code of Conduct on the Distribution and Use of Pesticides* (further referred to as the Code of Conduct) to guide development of such systems, and have found the various implementing guidelines to be very helpful. These nations seek human health and environmental protection from the risks of pesticides for their people and access to safe and effective products for their agricultural and other users of pesticides. However, even the best designed and most comprehensive regulatory systems cannot accomplish their purpose unless there is real, meaningful compliance with their requirements. Mere paper requirements can create a false sense of security.

It can be very difficult to achieve widespread compliance with a regulatory system. Compliance requires competency and expertise, involves costs, and comes only when regulated entities have a willingness and even a commitment to invest the resources and efforts necessary to comply. This will almost always require the involvement of government and the establishment of government enforcement programmes.

Governments face considerable challenges in finding ways to motivate compliance successfully, and generally have to establish an approach to compliance and enforcement using a variety of tools and over a period of time. There is no single effective formula for achieving compliance. There is only trial, evaluation and feedback, and attention to what works and what does not work in each specific situation. Getting started with enforcement programmes can be a discouraging task, and it is important to consider that some enforcement is better than no enforcement, and that every government has to start somewhere and build from available structures and tools.

The framework consists of two major parts: **core principles** (Section 2) and **the building blocks** for implementation (Section 3). Ten Core Principles (Sections 2.1-2.10) are the foundation for the design and implementation of pesticide compliance and enforcement programmes, providing basic information about the policy and theoretical framework for achieving compliance. The guidance for establishing an effective compliance and enforcement approach at the national level (Sections 3.1-3.8) includes suggestions for means to assure effectiveness and public accountability. This section includes the major steps or elements which must be considered as each nation's particular approach is put together. Success depends on evaluation of results and continuous feedback to adjust and improve. Measures of success include activity measures, compliance measures, and environmental and public health measures.

The Appendices to these *Guidelines* provide additional detail to assist in developing some of the key legal and institutional aspects which can go into the overall enforcement approach as it is being developed in each country. Appendix A covers legal tools and instruments. It provides specifics about how to make pesticide requirements enforceable and how to establish the legal authorities necessary to conduct enforcement activities (see box). The Appendices are provided for use primarily by persons responsible for operational implementation of the specific details of the programme.

This guidance document is designed to collect in one place and provide a reasonably comprehensive source of compliance and enforcement guidance to support implementation of the International Code of Conduct. The references section of these *Guidelines* also contains information about a number of

other publications that may be useful to nations seeking guidance on the implementation of pesticide compliance and enforcement programmes.

## **Appendix A. Legal tools and instruments**

**Appendix section A.1** covers making requirements enforceable. It describes the importance of requirements that are possible and practicable to achieve and explains the lack of respect for compliance that comes from being too stringent, depending on inaccessible technology or trying to be effective too quickly. On the other hand, it encourages high standards as long term goals. It offers ways to avoid loopholes and unclear provisions and emphasizes language that imposes a duty (e.g. use of “must” vs “should”). This section addresses detectability and measurability.

**Appendix section A.2** covers defining illegal acts, emphasizing clear statements on what acts and omissions are required. It explores examples like specific terms and conditions of pesticide registrations and labels and clarity about controls on sale and use of un-registered pesticides.

**Appendix section A.3** covers investigation authorities like inspections and monitoring. It explains the importance of a full range of legal authorities even with limited resources and it includes details like entrance to premises, sampling and interviewing as well as specifics for requiring self-monitoring and recordkeeping by pesticide makers and/or users.

**Appendix section A.4** covers the various legal means to respond to problems and violations. These include emergency response authorities (to correct an imminent hazard or stabilize a threat), order authorities (to mandate steps for compliance), and sanction authorities (to punish and deter violators). This appendix section provides detailed specifics about the various types of these authorities, such as administrative and judicial procedures, civil and criminal sanctions, and identifies other types of government controls.

## **Appendix B. Institutions, infrastructure, resources and expertise necessary for enforcement capacity**

**Appendix B.1** focuses on the agency where the enforcement programme is located, and explores options about where to locate compliance functions within the larger structure and how to coordinate and collaborate with other entities. It considers what functions and expertise to co-locate (e.g. lawyers, laboratories, compliance promotion) and identifies pros and cons. It helps the programme designers decide whether the pesticide enforcement programme should be “all-in-one” or not.

**Appendix section B.2** is devoted to issues regarding inspectors, covering background, status (public service or contracted), extent and type of specialization, and nature of duties. In all of these areas, advantages and disadvantages of various choices are explored. As a central player in enforcement, the inspector’s competence and credibility are crucial to programme effectiveness.

**Appendix B.3** covers equipment and laboratories. This section explains the range of equipment needs, from start-up needs like transportation, cameras, record books and basic safety equipment through complex capabilities like full-service laboratories. It explores ways to evolve with time and resources, and emphasizes information resources like libraries and on-line capacity.

**Appendix section B.4** explores specialized expertise in science, law, and administrative fields. It identifies disciplines like chemistry, finance, marketing and computer professions which may be important. It discusses various approaches to developing and using lawyers.

Appendix B concludes with sections on independence and **professional integrity (B.5)** and on **coordination (B.6)**, with techniques on how to enhance these factors.

## 2. Core principles of compliance and enforcement

### *Ten Core Principles*

1. Full and Continuous Compliance as the Goal
2. Culture of Compliance
3. Clear and Well Understood Requirements
4. Expectation of Self-initiated Compliance
5. Likelihood of Detection of Violations
6. Fair and Predictable Government Response
7. Level Playing Field
8. Message Sending and Deterrence
9. Comparable Treatment for Public and Private Sectors
10. Transparency and Accountability

In this section, the fundamental policy and theoretical underpinnings of any compliance and enforcement approach are briefly discussed. This section is provided so that each government can approach the more particular discussion of how to design and establish enforcement programmes within the context of the underlying behavioral and motivational considerations that inform such choices. While there are profound cultural and institutional differences among peoples and nations, these core principles have proven to be remarkably consistent across cultures and governmental systems. The pesticide enforcement programme should be based on these principles.

### **2.1 The goal is immediate, full, and continuous compliance**

This principle states the goal, or optimum desired state for any programme of compliance with pesticide requirements. Almost no system will completely achieve this ideal state. However, it is important to maintain a vision of the fundamental goal. It has three key components: immediate compliance, full compliance, and continuous compliance.

Immediate compliance refers to the expectation that, at the point that new requirements become fully effective, regulated entities will begin immediately to comply with those requirements. It is often desirable to delay the effective date of new requirements so that there can be a period of education and building of capacity for compliance. Requirements can be phased in over a period of time, with some that are simpler or more critical becoming effective earlier than others. However, at the point in time designated for the requirement to be implemented, the goal of the compliance programme should

be for regulated entities to begin compliance at that point, rather than waiting for government to further assist, cajole or demand compliance.

Full compliance means compliance with all applicable and relevant requirements, rather than some portion of the requirements or to some degree or fraction of each requirement. Requirements should be set in a manner that is technologically and economically possible (though not necessarily easy) and the compliance programme should be designed based on the principle of achieving complete compliance.

Continuous compliance means that regulated entities are expected to comply with the applicable requirements at all times, regardless of season, time of day, or other operating conditions. Requirements may be written so that they vary under certain changing circumstances, like climate or weather conditions, but the goals of the compliance programme should be to achieve compliance with the requirements as they are written. Regulated entities should not move in and out of compliance over time.

## **2.2 An overall culture of compliance is critical to achieving compliance goals**

Each government and people approaches compliance with law based on a wide range of cultural, historical and social factors. If pesticide compliance programmes are to succeed, there must be an acceptance of compliance with the applicable requirements as a business and social norm. In societies where respect for the rule of law is the prevailing norm, this may not be particularly difficult. Where those conditions are not present, it may be necessary to work very hard to build such an approach to pesticide issues. This may require significant awareness raising about the special risks and other considerations involved in pesticides management. International organizations and networks can be helpful in this effort.

## **2.3 Compliance goals are most achievable if requirements are clear, widely known and understood**

Even when there is a strong culture of law-abiding and legal compliance, programmes to achieve compliance may not succeed if the requirements are not plain and clear and capable of being followed. The duties of each affected entity must be understood, so that both the regulated entity and the government can readily identify what constitutes compliance. Information about the requirements must be easily available to the affected parties, in a form they can fully understand. Efforts to increase access to information about the requirements and the tools, equipment, or expertise necessary to comply are very important.

It is best when the regulated community and the general public not only understand what the requirements are and how to comply with them, but also the reasons for such requirements. Knowing the reason for requirements can help develop both the capacity and the willingness to comply.

## **2.4 Regulated entities should see self correcting activities as preferable to government detection**

In general, compliance is best under a system where regulated parties take the initiative to comply with requirements without the intervention of government. Government does not have the resources

or the time to take each entity by the hand and direct it into compliance. Therefore, the compliance system must be built so that regulated entities do not await government detection before they start compliance efforts. This is more likely to occur when there are sanctions for those who wait for government detection—when the threat of government action deters violators from choosing to violate.

## **2.5 There should be a reasonable likelihood that violations will be detected by or brought to the attention of government**

In order to design a system where the potential violator decides that it is better to comply than to wait for government detection, it must be reasonably likely that government will detect the violation. There are many tools available to enhance the ability of government to detect violations. First, requirements should be designed so that violations are easier to detect. Then, systems must be in place to increase the opportunity for detection, whether through systematic inspections, unpredictable inspections, tips and complaints from observers, or required self-reporting mechanisms.

## **2.6 Governmental response to violations should be fair, predictable and proportional**

A culture of compliance also requires that all affected parties have confidence in the integrity and competency of the governmental response when violations are detected. In general, the government action should be enough to create incentives to comply, but consistent and fair so that the action is viewed as legitimate. The severity or harshness of the governmental response should be a function of the magnitude of the violations, the frequency or duration of the violations, and the compliance history and approach of the violator. Accused violators should be able to contest the government's assertions of fact and law, and there should be an efficient, fair means to resolve any disputes.

## **2.7 There should be a "level playing field"—no comparative economic advantage to non-compliance**

If one member of a regulated industry or sector can gain a competitive advantage by choosing to violate the law, this creates a situation where all members may feel pressure to avoid the costs of compliance. Complying entities will, at a minimum, feel considerable resentment about unfair competition, thus undermining the culture of compliance. In order to assure a level playing field, government should work toward compliance by all affected entities and respond to detected violations in a way that eliminates competitive advantages from violations. For example, monetary fines or penalties should be sufficient to offset economic gains from the violation.

## **2.8 Governments must send messages that will encourage deterrence, including publicity on violations**

Government cannot identify and correct every violation; it must maximize the impact of each action through priority setting and message-sending, including widespread publicity for governmental responses to violations.

If other violators or potential violators are to be motivated by the consequences that result when government detects and responds to violations, they must know about them. Publicity can be general, e.g. public media, or targeted, to trade publications and industry or sector conferences or meetings.

## **2.9 Public and private regulated entities should have to play by the same rules with similar consequences for non-compliance**

Certain pesticide requirements may apply to both public and private entities. For example, use directions contained on labeling may be binding on private agricultural operations as well as publicly funded farms or enterprises. In those circumstances, it is important that both kinds of entities be expected to comply in the same manner and to the same extent, in order to promote the culture of compliance and to achieve the desired health, safety and environmental protections. It is often difficult to operate an enforcement programme that is applied to another government entity, but it is critically important to design comparable programmes and responses for the public and the private sector.

## **2.10 Government should be transparent (consistent with law enforcement needs or confidentiality and with rights of private parties) and accountable**

Respect for government is a crucial component of any successful compliance programme. Success in design and implementation of such programmes depends on evaluation of results and continuous feedback to adjust and improve. All of these elements depend on openness and transparency. The regulated community and the general public alike need to be able to see and understand what activities government is undertaking to achieve pesticide regulatory compliance, how those actions are working, and what results they are achieving. There are certain stages in the investigation of violations where confidentiality can be important, and it is also important not to publicize violations before there is a sound basis for public statements about such violations. Public information should be fairly presented and include information about any challenges or appeals by alleged violators. With these limitations, however, government should seek to maximize the availability of information about the design, conduct, and results of its compliance and enforcement programmes.

### 3. Designing and building the compliance and enforcement programme

Elements of an Effective Compliance and Enforcement Approach.

#### *Eight building blocks for programme implementation*

1. Clarifying roles and responsibilities
2. Creating enforceable requirements
3. Knowing and understanding regulated entities
4. Planning and setting priorities
5. Promoting and encouraging compliance
6. Monitoring compliance
7. Responding to violations
8. Evaluating programme success
- 9.

In this section, the *guidelines* go through each of the key steps in developing a national approach to pesticide enforcement. Each step is relevant to every such programme, whether it is at the beginning stages and must be limited to a few critical activities or it is already well established.

After each step, one or more examples of national implementation approaches are presented. These are identified as hypothetical countries (A, B, C, etc.). Each hypothetical country remains the same throughout the section. For example, the Country A in Section 3.1.5 is the same country as Country A in Section 3.2.2. The country examples carry forward, so that the various pieces of each strategy for, say, Country A, can be combined to form an example of overall national strategy.

#### 3.1 Clarifying roles and responsibilities

As a part of establishing a national pesticide regulatory programme, each nation will have already faced many organizational and governmental structure issues. It usually will have chosen one particular ministry (most likely health, environment or agriculture) to house the primary elements of its programme and will have identified the need for coordination with and perhaps sharing of responsibilities with other ministries and organizations, including, in addition to the three mentioned above, customs and trade, transportation, labour, justice, consumer protection, and perhaps others. Determining respective roles and responsibilities is likely proving to be an on-going challenge, at least for some aspects of the programme. The initial choice of how to structure the national approach

undoubtedly involved a series of trade-offs, advantages and disadvantages. With experience, the disadvantages may become increasingly apparent and even threaten the fundamental effectiveness of the structure.

While every nation is continuing to work through the challenges of defining roles and responsibilities, establishing the enforcement component of the national programme can appear to even further complicate the dynamic. For example, the primary pesticide regulatory programme may have been located in the health or environment ministry because of expertise in areas like chemistry and toxicology. However, compliance and enforcement activities rely heavily on field-level expertise and on an understanding of the processes for manufacturing, marketing and using pesticides. This kind of expertise may be difficult to find or even to develop within the same organization. On the other hand, when the regulatory programme is housed in the agriculture ministry, for example, precisely because of expertise in operational agriculture, that ministry may have little existing formal enforcement structure, especially if the role of the ministry has been traditionally limited to supporting and facilitating agricultural production and trade.

There is no single right answer to the issue of where to locate a pesticide regulatory enforcement and compliance programme. However, several factors will help to inform the choice. This section provides guidance on the key factors that will assist in clarifying roles and responsibilities for pesticide compliance and enforcement functions. Sorting through who is to have what responsibilities and how they will communicate, share information, and work together is critical at the outset and on an ongoing basis. This section recommends ways to decide these issues.

### *3.1.1 Sources of funding and resources*

As a purely practical limiting factor, each nation will have to determine the source of funding for its pesticides enforcement activities. The answer to this question may significantly affect the assignment of roles and responsibilities. Basically, funding can come either from re-programming of existing resources or from some new source of funding. The two most likely re-programming sources are either existing pesticide regulatory resources or existing (non-pesticide) law enforcement resources. New funds could be generated from general revenues; from taxes, licensing or other fees imposed on pesticide manufacturers, importers, or sellers; from taxes or other fees imposed on pesticide users; or from penalties and fines collected in connection with enforcement actions against violators. These alternatives can be combined in a number of ways. A staple source of funding from some combination of fees and public funds is usually best.

While these choices do not necessarily dictate the allocation of roles and responsibilities, they are likely to have a practical effect. If, for example, existing law enforcement resources are going to be the prime source of pesticide enforcement funding, then it is more likely that at least key parts of the pesticide enforcement programme will be co-located with existing inspection, investigatory, police or prosecutorial authorities, perhaps in related organizations and subject matter, like environment, food safety, or customs. Conversely, funding by diverting funds from existing pesticide programmatic activities will create pressures to combine the programmatic and enforcement functions in some structural way.

While it is understandable that the source of funding would affect the allocation of responsibilities and roles, it is recommended that the other factors identified in this section be considered as well.

### *3.1.2 Common expertise, policies, and activities*

As indicated at the beginning of this Section 3.1, institutional location for the pesticide regulatory programme will already have been addressed in nations that have begun establishment of such programmes. It is important to locate the compliance and enforcement programme in a way that facilitates coordination, joint planning, and sharing of expertise with the other aspects of the pesticide

regulatory programme. It can also be desirable to have some amount of independence from the regulatory programme, so that enforcement activities have their own focus and so that there can be efficiencies from combining pesticide enforcement activities with enforcement for other, related programmes. Enforcement for export and import requirements will almost certainly require involvement of customs officials in some way, while enforcement of transportation requirements needs to involve transport officials. Labor officials (for requirements applicable to workers), health officials (for requirements relating to poison reporting, for example), and, of course, justice ministries (for formal, judicial enforcement activities) may all be relevant or even necessary players. In other words, there is no organizational answer that would eliminate the need for cross-organization coordination. Task forces, special multi-organizational teams, and clear divisions of responsibility are all recommended approaches.

Another important factor affecting structure, roles and responsibilities is regional or multinational organizations, networks, and agreements. Many national-level compliance and enforcement activities can be greatly enhanced by cross-border cooperation. While this is particularly important for enforcement of requirements designed to implement international conventions and other cross-border regulatory requirements, it is also useful where the pesticide industry and pesticide users have a common identity or similar activities and practices on a regional or multinational scale. Cross-border cooperation can be greatly helped by similarity of structure and division of responsibilities in cooperating nations.

### *3.1.3 Centralization/decentralization*

Most nations will have assigned the core pesticide regulatory programme functions to the central government, although certain aspects may be managed at the provincial or local level, such as the training of pesticide applicators. The same division of responsibility based on level of government may be appropriate for the compliance and enforcement function, but there could be important differences. While some degree of centralized planning and national-level oversight to address consistency, fairness, and integrity may be necessary, many law enforcement type activities are typically carried out at lower levels of government. Import and export controls or the obligation to obtain a national licence or registration will require enforcement at the national level. It is practical to envision a role for lower levels of government in monitoring compliance and responding to violations for most sales, use, and disposal requirements. One recommended approach is to assign dual responsibility, so that the national level government and provincial or even local governments have parallel roles in investigating and/or responding to violations. This would allow the national authority to operate in more complex matters, when the violators cross provincial lines, when specialized expertise is needed, and where necessary to assure adequate consistency throughout the country. It would also serve to develop capacity at the other levels of government, take advantage of existing resources and infrastructure, and provide for visibility and accountability at the governmental level closest to the problems. The degree of overall operational direction from the central government should depend on development and capacity of lower levels of government.

### 3.1.4 Sample national implementation (Countries A,B,C)

#### Country A example:

Country A has a pesticide registration programme located in the Ministry of Health. While the location of the registration programme has been established, work on legislation is not complete and there is no current national pesticide enforcement structure. The Ministry of Health has a small Inspectorate which enforces other health-related requirements.

Country A locates the pesticide enforcement function in the Inspectorate for the Ministry of Health, assigning management and planning to existing leaders in that Inspectorate. Two inspectors are reassigned to pesticides and will be provided with re-training. They report through the management chain of the Inspectorate. The Inspectorate managers form a task force with border control personnel from the Customs Office, field specialists from the Agriculture Ministry, laboratories operated by the Ministry of Environment. The attorneys and administrative support systems used by the Health Inspectorate are also involved. Together, the managers in the Health Ministry Inspectorate and this task force will plan and carry out the pesticide enforcement programme.

#### Country B example:

Country B has a pesticide registration and operator training programme located in the Ministry of Agriculture. There is no current national pesticide enforcement structure and the Ministry of Agriculture does not have an inspectorate and does not currently have any enforcement functions.

Country B co-locates the enforcement function with the registration and operator training programme, dedicating a small group of personnel exclusively to enforcement activities, with overall management and administrative support supplied by the pesticide regulatory programme. This group is provided with inspection and enforcement authorities. This small group develops a net-work of resources and develops joint activities with the Customs Office, the Inspectorates for Health and Environment (including their analytical laboratory), other parts of the Agriculture Ministry, and the Justice Ministry. Using this net-work, coordination, and shared information, the small group plans and carries out the overall enforcement programme.

#### Country C example:

Country C has a small existing pesticide enforcement programme as part of its registration programme. The current activities are limited to cross-border enforcement and the monitoring of whether wholesale pesticide sales are properly registered products.

Country C uses one or two persons in the national government to design and support a provincial level programme for the monitoring and enforcement of retail sale and use of pesticides, providing model provincial legislation, training, and coordination services. After a period, this kind of enforcement (retail sale and use) becomes primarily a provincial function, with some national-level planning and tracking.

## 3.2 Creating enforceable requirements

### 3.2.1 Necessary elements for enforceability

No enforcement programme can work and no compliance goal can be achieved unless the requirements are plain, clear, and capable of being followed. It is very important to devote efforts to assure that the statutes, regulations, licences, and labels are written in a way that makes it clear what duties are imposed. The duties of each affected entity must be readily understood, in a way that both the regulated entity and the government can readily identify when there is compliance (and when there is a violation). To be enforceable, legislation or implementing regulations must make it clear who is required to act (a manufacturer, a seller, the user of the product, etc.) and what he is required to do or not do. It must be possible to detect and demonstrate when and where a requirement has been violated. It is generally preferable to define illegal acts separately and distinctly.

Another critical element of enforceability is making sure government has the necessary authority to detect and respond to violations. Either through existing law or through separate added provisions, there must be adequate authority to conduct inspections, obtain evidence (including product samples and witness testimony), and respond to violations in order to require compliance and impose sanctions for violations.

There are a range of methods for providing these authorities, under civil and criminal law, with or without the involvement of the judiciary, and with a variety of types of safeguards to assure due process. More details on these authorities, and the pros and cons of each are provided in Appendix A.

Finally, and particularly important for newly developing regulatory and enforcement programmes, standards should be set so that they can effectively be followed with the resources and sophistication of the regulated entities. If pesticide users cannot obtain and handle complicated protective equipment, the registration authority should consider not allowing use of pesticides that can only be safely used with such equipment. Similarly, if crops cannot be grown using available agronomic practices without field worker entry into treated fields before residues have declined to safe levels or if harvests cannot practically be delayed until food residues have declined to acceptable levels, it is better not to allow use of those pesticides on such crops. It would not be workable to try to enforce re-entry intervals or pre-harvest intervals that simply cannot, as a practical matter, be complied with.

### 3.2.2 Sample national implementation (Countries A,C,D)

#### Country A example:

Country A has not yet completed its implementing legislation for its pesticide programme.

Country A, under the joint lead of the pesticide regulatory programme and the inspectorate, convenes a group of government experts, including technical experts and attorneys who, after consultation with NGO's and the private sector, identify the aspects of the pesticide law that need clarification in order to assure that the provisions are well understood and impose clear duties. This government group also evaluates what tools and authorities need to be authorized for the inspectorate and other enforcement personnel in order to be effective. These provisions are then introduced into the legislation.

#### Country C example:

Country C has already put in place its regulatory and enforcement programmes and the implementing legislation. The regulatory programme relies on the registration or licensing of individual pesticide products and the labeling of products with the required terms and conditions of use.

Country C undertakes a special effort of training, template design, and model licences and labels in order to improve the wording and other aspects of the licences and labels to make them clearer and more enforceable for all its future registration activities.

### **Country D example:**

Country D has not yet fully developed its pesticide registration programme. It has mostly small farms and the national agricultural economy is not equipped for complex technology inputs.

Country D develops a system that will only authorize for sale and use those pesticides which can be safely handled without major or complicated packaging, equipment, or use directions. Such pesticides are clearly defined and specifically named. The national legislation requires that all importers and all wholesale sellers of pesticides demonstrate that they know what pesticides are registered for use in the country and report annually to the government all imports or sales of all pesticides.

## **3.3 Knowing and understanding regulated entities**

### *3.3.1 Steps for understanding the regulated community*

Knowledge of and understanding the nature of all participants in the life-cycle of pesticides is a challenge for even the most well-developed pesticide programme. An important step in determining how to set priorities and develop enforcement capacities is to identify what groups are regulated and to understand as far as possible their sophistication, ability, motivation and willingness to comply.

The pesticide industry consists of a few, major multinational corporations and a multitude of smaller firms who may manufacture post-patent ingredients, formulate end-use products, or repackage already formulated materials. The channels of trade in pesticides may include intermediaries, jobbers, exporter/importers, wholesale establishments and retail establishments, including multi-facility chains, very small private establishments, cooperatives, internet or catalog-based sellers, and outlets that also market a wide variety of other goods and services. Users of pesticides range from professional applicators and very large agricultural or industrial users to individual small farmers or home dwellers.

A newly developing pesticide enforcement programme will want to focus on understanding the key regulated entities and/or the entities likely to present the greatest problems and risks. Trade associations or business representatives may be helpful for information about some types of entities. Other governmental agencies that work with these sectors of the economy may have contacts and expertise that can be useful. Unions, farmworker groups, and other NGO's may also provide valuable

insights. Regional and larger international networks may be helpful, especially where the regulated industry is transnational. Use of all these sources of information is recommended.

Understanding the pressures and situations which affect the motivations of users and lead to use violations can be helpful in preventing and controlling pesticide misuse. Among such factors are the following: 1) complexity of requirements and a tendency to simply give up and ignore complex requirements; 2) difficult conditions, such as unusual weather or unusual pest pressures; 3) economic factors, especially if costs of inputs are high and prices for commodities or services are low; 4) inertia, or a tendency to continue doing things in familiar ways after requirements change; and, on the other hand, 5) an eagerness to use new technology, even though it is not authorized. This latter situation can arise when a new and promising pesticide is registered for use on some crops but not on others or when a new diluent or application method becomes available, but the pesticide labeling does not allow the use of such technology. This situation can be made worse if a pesticide is legally available elsewhere, such as a neighboring country, or if the marketers of new technology improperly promote it for unlawful uses.

### *3.3.2 Sample national implementation (Countries A,B,D)*

#### **Country A example:**

Country A focuses first on understanding the business structure for the importers and sellers of pesticides. It develops an inventory of businesses involved in import, wholesale sales and significant volume retail sales, complete with detailed contact information. This will allow Country A to develop a strong capacity to assure that all the pesticides used in the country are properly evaluated and registered. Country A has had some problems with high levels of pesticide contamination in the rivers and streams of certain regions, and with areas of disposal of partially filled containers and resulting exposure to children playing around such disposal areas and with soil contamination. Therefore, Country A's Health Ministry (pesticide programme and inspectorate working together) embarks on a special project with the Agriculture Ministry to better understand how the marketers and users of pesticides plan for and handle unused product left in containers and containers ready for disposal.

#### **Country B example:**

Because Country B's pesticide enforcement programme is located in the Agriculture Ministry, Country B makes a special effort to supplement its expertise in agriculture by using the knowledge in the customs service and the Trade/Commerce Ministry to help the programme better understand the structure and nature of the import and wholesale portions of the pesticide industry. Country B develops a list of key businesses and trade groups involved in this part of the business, which is maintained and updated jointly by the Agriculture Ministry and the Trade/Commerce Ministry. Country B also takes advantage of the expertise in the Health Ministry and the Ministry of Consumer Affairs to better understand the use of pesticides in commercial buildings, schools, and homes.

### Country D example:

Country D believes that it has addressed many of the potential concerns about pesticide users by limiting the scope of products legally available for use. Therefore, Country D works hard to understand how and by whom there could develop a black market in unregistered pesticides, concentrating on both potential import points and potential sales points for illegal products. The customs officials and the police are included in this effort to analyze situations where unregistered pesticide sales may be likely.

## 3.4 Planning and setting priorities

### 3.4.1 Elements of planning and priority setting

No enforcement programme can attend to every regulated entity at all relevant times. Choices must be made; for new and modest programmes, choices are fundamental. Further, any compliance strategy, whether basic or comprehensive, requires a series of activities over time, often building on each other and determined by what came before. This kind of sequencing also requires planning. Therefore, planning and priority setting make up a critical element of every programme.

Priorities must be set and choices must be made in several different aspects of the enforcement programme. The programme must determine what requirements or sectors of the regulated community to concentrate on. One priority approach would attempt a relatively thorough and comprehensive effort for a very limited segment of the range of requirements, such as import controls. Another would attempt to have some limited presence across a much broader range of requirements, including import, wholesale sales, retail sales, end-use, and disposal. If this latter, complete life-cycle approach is attempted, the priority-setting process could focus on a few types of pesticide products or those for a few crops, in both cases where there is the greatest potential for risk, for misuse, or for larger numbers of exposed persons, such as workers.

For example, if some of the higher-risk insecticide products are manufactured by smaller less-established companies and are used in crops with a lot of field workers who come into contact with the post-application residues, these particular pesticide-crop combinations could be a good choice of a higher priority for an enforcement focus that includes import, sales, use, and disposal. On the other hand, if the primary concern is the lack of integrity of the manufactured product, then the focus should be limited to import and sales. Similarly, if the primary concern is handling and disposal, enforcement activities would not need much attention to import or sales of such products. It is recommended that priority setting be based on a combination of risk factors and areas of greatest known problems. Recommended priority areas for developing countries include product quality assurance, manufacturing source authenticity, treated product residue controls, and occupational exposure protections.

Each enforcement programme must also consider what fraction of the enforcement effort should be responsive to tips, complaints, poisoning or other incidents and what portion of the effort should be specifically chosen and targeted by government. In general, governments need to be responsive to reports in order to promote the culture of law-abiding, to reinforce helpful reporting, and to establish governmental integrity. For these and other reasons, it would be inappropriate to completely eliminate response to tips and complaints as a driving force in choice of where to devote energies. However, this approach alone can lead to priorities that do not relate to the highest risk or even to the highest areas of violations. For example, economic competitors may do a very thorough job of reporting

violators in their industry segment, even if those violations are not particularly important from a risk point of view. On the other hand, there may be no-one with the knowledge or motivation to report violations with significant impacts on ecosystems, even if the impacts could be readily identified. Some observers of violations, such as workers, may fear reprisal for reporting violations. Some situations, such as pesticide poisoning, may not be accurately diagnosed and therefore could not be reported. It is recommended that each government set aside some portion of compliance and enforcement resources to devote to priorities that it identifies through means other than tips and reports so that the limited available resources do not all go to activities to respond to such reports.

In a third important element of priority setting, choices will also be necessary among available types of activities. What portion should be devoted to information sharing, instruction, and compliance promotion and what portion should be devoted to monitoring, investigation, and detection of violations? What level of effort is appropriate to respond to detected violations, and what specific types of detected violations should get what level of effort? The answers to all of these questions will depend on such things as 1) how new the requirements are (newer = more information and compliance promotion); 2) how widespread the violations are (widespread and knowing = more monitoring and stronger responses to discovered violations; widespread and unintentional = more compliance education); 3) how severe the violations (more severe = stronger response to detected violations); 4) how intentional the violations (less intentional = more instruction and information sharing). These are just a few examples of the factors that influence the choice of activities. Of course, at a very practical level, the scope of activities will be limited by the skills, tools, and resources available. If there are very few inspectors and they cannot travel to many use locations, inspections can be conducted only to the extent there is a capacity for that choice. Under those circumstances, all the aspects of priority setting become even more important.

Planning and priority setting can also be informed and enhanced by international cooperative efforts, regional networking, and harmonization. While this is particularly important for enforcement of the regulatory requirements designed to implement international conventions, it is also very useful for all cross-border regulatory requirements and for situations where the pesticide industry and pesticide users are the same or similar on a regional or multinational scale. Wherever practicable, this kind of regional and international coordination is recommended.

Once basic determinations are made about priorities and focus areas, many activities require significant advance planning. Before inspections are initiated, plans will need to be in place for follow-through activities. If violations are found, plans will have to include the necessary steps to correct violations, and, if appropriate, impose sanctions. Good programme management requires planning for budgeting, accountability, and appropriate publication of activities and accomplishments. Planning and priority setting need to be built into every compliance and enforcement programme, regardless of size or age.

### 3.4.2 Sample national implementation (Countries A,B,C,D)

#### Country A example:

Country A has a three year planning cycle, which it has coordinated with the other nations in its regional network. In broad terms, it will focus in year one primarily on completing legislation and on working toward enforceability of its implementing regulations, licences, and labels. The Inspectorate will begin compliance monitoring relating to imports and to disposal activities, and will respond to violations using the same personnel and expertise that is currently developing enforcement responses for other kinds of violations within the health ministry inspectorate. In year two, country A will expand its compliance monitoring activities to include large wholesale and retail sales operations and large-scale agricultural and other commercial pesticide users. It will develop outreach and compliance assistance materials aimed primarily at small and medium sized businesses and users. By year three, it will have developed measures of the scope of the disposal problem and the effectiveness of the activities it has undertaken to address the problem, and will begin to evaluate its experience with enforceability of the enacted legislation, regulations and licences. Compliance monitoring and enforcement response capacities will continue to focus on imports, disposal and larger enterprises, with some beginning investigation of the compliance status of small and medium sized sellers and users of pesticides. Experience with compliance monitoring and enforcement response will be evaluated to determine where additional training, equipment or expertise may be needed.

#### Country B example:

Country B is building its enforcement function without any history of related enforcement activities and expertise within the Ministry. Therefore, it has a two year plan in which, for year one, it concentrates on training, networking with other, experienced enforcement organizations elsewhere in the government and limited initial implementation activities, involving a carefully planned limited number of inspections, with extensive follow-up evaluation and feedback learning. If violations are found, expertise from other governmental offices will be solicited to help with preparing appropriate responses. In year two, Country B begins the development of a strategic approach which includes carefully targeted expansion of its compliance monitoring and inspection activities together with further capacity building for compliance promotion, inspection, and use of compliance orders and sanctions.

#### Country C example:

Country C focuses on working with the provinces to develop coordinated plans for each province that contain a mix of national consistency and special emphasis based on the particular circumstances of each province.

## Country D example:

Country D puts together a special task force from various government Ministries with relevant expertise (such as police, prosecutors, customs officials) to develop a strategy to identify and pursue black marketers in unregistered pesticides. It also plans and develops an outreach and voluntary training programme for users of pesticides, designed both to prevent the use of unregistered pesticides and to improve the capacity and competency for use of the available registered pesticides.

## 3.5 Promoting and encouraging compliance

### 3.5.1 *The role of compliance promotion*

Building the capacity to comply and motivating regulated entities to choose compliance are essential elements of a successful compliance programme. Enhancing user and public understanding of the nature of pesticides, the risks involved in their use, the alternatives available to manage pest problems and the options available to limit exposure to pesticides and manage their risks should be used to promote safer pesticide use and compliance with applicable requirements. It is helpful for all affected persons to know not only how to comply but *why* compliance is important. Where international conventions are involved, it is desirable for people to understand that a nation's international prestige will be enhanced if there is compliance with the requirements.

Strong and effective training programmes are key elements of pesticide regulatory programmes and can also significantly improve compliance. Training may be voluntary or the sale and use of certain pesticides can be restricted to persons who have received designated training. Users of certain pesticides may be required to train their workers as part of the conditions of use of those pesticides. In cases where training is mandatory, compliance with the training requirement itself becomes an important task for enforcement. Training should be well-designed, understandable to the trainee, periodically reinforced, and measured as to its effectiveness.

Affirmative incentive programmes may also contribute to compliance ability and willingness in the regulated community. Economic or technical assistance could be linked to training or directly to proof of compliance with certain requirements. Special opportunities for marketing or advertising of products could be designed to reward those with strong compliance records. Self-reporting and self-correcting of violations can be treated more favorably than government-discovered violations. Although government must be very careful about appearing to endorse or approve activities which it may not be able to adequately assess, carefully designed incentives can be a healthy part of compliance programmes.

Compliance promotion is most useful where there is already a general willingness to comply with pesticide requirements or where encouragement is effective. Usually, only some portion of the regulated community will respond to these approaches alone. It is recommended that these approaches be used primarily when introducing new requirements, when establishing requirements applicable to a new or different group of regulated entities, and in conjunction with approaches that sanction those who do not choose to comply.

Because activities to promote and encourage compliance usually do not involve adversary procedures or trigger due process rights, these activities can be conducted by different parts of the government than more legally sensitive activities like formal inspections and civil and criminal enforcement. In fact, some amount of separation is recommended. However, it is important that such activities be

consistent with and planned in concordance with more legally formal enforcement programme activities. Strong and continuous communication and coordination are also important.

### 3.5.2 Sample national implementation (Countries A,B,D)

#### Country A example:

Country A has decided to provide extensive compliance information and assistance to small and medium sized businesses and users. It works to prepare informational materials, conduct “train the trainer” sessions for business organizations, worker organizations and NGO’s, and develop an internet site and a hotline for answering compliance and related questions. The project is a combined activity of the Inspectorate and the pesticide registration programme, both of which are in the Health Ministry. The Inspectorate officials believe that, at some future time, it will be appropriate to conduct compliance monitoring activities in these sectors and that entities that continue to violate after having had the benefit of so much opportunity for compliance assistance should receive a strong enforcement response.

#### Country B example:

Country B is working to determine what kind of infrastructure and legal tools it will need to best design compliance promotion activities. It is exploring ways to link government assistance programmes and government-subsidized loans with training for and compliance documentation from recipients. It is also discussing with private insurers and banks ways they can encourage and reward good compliance records. It is working to design effective training programmes that involve evaluation of their effectiveness. In all of these activities, it takes advantage of the agricultural sector expertise within the Agriculture Ministry and seeks assistance from other parts of government with expertise in the other affected sectors.

#### Country D example:

Because Country D has limited the pesticides it registers to those which can be reasonably safely handled without complex expertise, Country D is devoting much of its limited compliance and enforcement resources to educating and assisting pesticide users to assure that they can identify unregistered pesticides and avoid their use. This effort is supplemented with efforts to improve the ability of users to follow label instructions and properly manage the storage, handling, and disposal of registered pesticides. All available sources of expertise, including agriculture extension agents, schools, and community leaders have been enlisted to help with this effort.

## 3.6 Monitoring compliance

### 3.6.1 Aspects of compliance monitoring

In order for compliance and enforcement programmes to succeed, potential violators must decide that it is better to comply than to wait for government detection. (See also *Guidelines on Monitoring and Observance of the Revised Version of the Code* which contains a check list for monitoring key elements of monitoring implementation of the Code of Conduct.) This motivation cannot occur unless it is reasonably likely that government will, in fact, detect violations. In order to plan enforcement priorities, government must have some understanding of what are the levels of compliance for the various requirements and sectors of the regulated community. For both of these reasons, some kind of systematic monitoring effort is strongly recommended.

Monitoring can be based on record-keeping and self-reporting by regulated entities, incident or complaint follow-up, inspections or other investigations, and measurements of environmental conditions like pesticide residues on food or in water sources. It may be comprehensive (everybody reports) or sampled, targeted or random in design, regular or irregular in timing intervals, announced or unannounced. All of these variations have advantages and disadvantages, and should be tailored to the specific circumstances.

The appropriate approach for monitoring of import and export of pesticides may be entirely different from the approach for retail sales or for use. Monitoring can be simple and involve primarily visual examination and basic interviews or may be very thorough and involve sampling and analysis of samples and full evaluations of books and records. Where monitoring results in the detection of violations, it is important that it include the collection of evidence sufficient to demonstrate the violation.

Choices among the types of monitoring and the extent and nature of monitoring activities will depend on national capacity, priorities, and the nature of particular compliance problems. Programmes should start with very simple tools and techniques while they build the capacity for more sophisticated approaches. Regulatory requirements should be designed with the limitations of national monitoring capacities in mind.

### 3.6.2 Sample national implementation (Countries A,C)

#### Country A example:

Country A, which is still completing its pesticide legislation, has decided to place an emphasis on self-monitoring and reporting for certain aspects of compliance, specifically for integrity of formulations, import, sales, storage conditions, and disposal. This involves a requirement for all business involved in manufacturing and import to conduct sampling and maintain records that demonstrate that the chemical make-up of the manufactured or imported product complies with the licence/registration, and report this information periodically to the government. Similarly, all sellers of pesticides above a certain volume are required to maintain sales records documenting that the products sold are registered and are sold in accordance with any limitations required as a condition of the registration. All users of pesticides above a certain volume are required to maintain records of all disposal of empty containers and of unused product. Country A is working closely with the regulated industry sectors to design these record-keeping and reporting requirements in a way that is workable, not unduly burdensome, and likely to be credible. Country A is designing its governmental inspection programme to focus on evaluating, verifying, and investigating possible violations revealed through these reports or violations of the duty to maintain such records and provide such reports.

## Country C example:

Country C is working with its provinces to develop an approach to inspector certification, inspector training, basic safety and investigative equipment and all other elements of sound inspections. The provinces vary in existing capacity and some have much further to go than others. The national government is attempting to help each province conduct a needs analysis and identify the necessary capacity-building steps. The national government is developing regional laboratories to be shared across provinces and standard inspector training manuals and field checklists.

### 3.7 Responding to violations

#### 3.7.1. *After detection, designing the governmental response*

Put simply, once government has identified a violation, it must decide what to do about it. If violations are discovered and ignored, this would surely be entirely counterproductive to the goals of any compliance and enforcement programme. Therefore, at a minimum, the discovery of a violation should be expected to lead to its correction. While this might be obtained informally, it could require the use of formal legal process, like the issuance of an administrative or court order, the shutting down of a facility or revocation of a licence, or even the incarceration of a violator. The most extreme of these actions likely would only be necessary in rare cases.

The mere achievement of compliance in the case of each discovered violation, however, will not help to create an environment in which other potential violators choose to come into compliance before detection. If the only consequence of detection is compliance beginning at that point, there would be no reason to comply until after government discovery of the violations. For this reason -- the need to send a message to other potential violators (and to this violator for future potential violations) -- it is recommended that there be adverse consequences for those violators who are caught. Those consequences can include unfavorable publicity, monetary fines or penalties, loss of privileges, or, in the most serious situations, loss of personal liberty (imprisonment.)

While both the correction of violations and the imposition of sanctions are critical elements of a credible enforcement programme, there is a large range of seriousness of violations and of the reasons behind individual violations. It will not be practical or appropriate to consider a “one size fits all” approach for responding to discovered violations. At one end of the spectrum, some violations will be trivial, clearly the result of misunderstanding or mistake, or debatable, disputed, and not necessarily violations at all. On the other end of the spectrum, there will be a few violations that are extremely dangerous and damaging. For this first category, little or no response might be wholly appropriate. For the latter, immediate, forceful, and continuous response is required until the danger is stopped and the damage is addressed to the extent practicable.

The imposition of sanctions carries the potential for governmental abuse of power and requires both fairness and due process for accused violators. Both the will to use sanctions and public and regulated community acceptance of their use require that they be employed in a way that is fair, predictable and proportional. The severity of the sanctions should be a function of the seriousness of the violations, the number or duration of the violations, and the compliance history and approach of the violator. Sanctions should take into account the extent of economic advantage that the violator gained from not complying and the extent of any damage or harm that was or could have been caused by the violations. Accused violators should have the opportunity to contest the government’s factual and legal claims, and there should be an efficient, fair and prompt means to resolve any disputes.

Finally, it is important that other potential violators know about the adverse consequences that occur to violators who are detected. Publicity and other means of education are important tools in responding to violations. And, while government sanctions may not be the only consequences for those who violate pesticide laws, they are almost always a key element of motivating and ensuring compliance. It is worth mentioning here some of the other kinds of adverse consequences that can occur, which include adverse publicity and resulting loss of respect or loss of business success, private lawsuits of various kinds, refusal of banks and lending institutions to supply needed funds, refusal of insurers to provide coverage or increases in the cost of coverage, loss of other government or private sources of funds, and sanctions by private business associations or cooperatives. In areas where these approaches are effective motivators for compliance, government may not need to focus its energies or make significant use of its authorities.

### *3.7.2. Sample national implementation (Countries A,B,C,D)*

#### **Country A example:**

In developing its national legislation, Country A has attempted to assure that it will have a comprehensive set of legal tools available to respond to violations. It has worked to develop simple, straightforward administrative processes for the issuance of both emergency and compliance orders and for the imposition of penalties and has designed a process for administrative challenges and appeals. Country A has also included in its legislation the option of using the civil courts to obtain emergency and compliance orders and penalties, and has identified certain serious, willful violations as subject to the penal code.

Country A expects to gain experience using these authorities as it identifies violations and considers on a case-by-case basis the most appropriate response during the initial years of its compliance monitoring activities. It expects that most of its initial use of these authorities will be for violations of import and disposal requirements and for violations by larger, more sophisticated entities.

#### **Country B example:**

Country B hopes to use its early experience with compliance monitoring to help it understand what kind of violations are occurring and to develop an approach to responding to violations which is consistent and sustainable. Country B plans to set a goal of taking actions to obtain compliance within six months of discovery of violations and of determining whether and how to seek penalties no later than one year after discovery. Where possible, these activities will be coordinated and, if the use of legal authorities is necessary to obtain compliance, it will be combined with any penalty action.

### **Country C example:**

Country C has enough experience at the national level with responses to import violations and violations involving the sale of unregistered pesticides to study and evaluate its history of responses. Based on this evaluation, Country C is preparing a general enforcement response policy to improve the consistency of its responses and to align those responses more closely with the core principles for achieving compliance described in this guideline.

Country C also begins an effort to work with its provinces to help them develop enforcement response policies and approaches that will encourage internal and cross-province consistency and alignment with the core principles. The national government is sponsoring multi-province workshops and information sharing about compliance order and penalty practice. Public prosecutors have been encouraged to network to promote common and sound practices for the use of criminal sanctions.

### **Country D:**

Country D has been concentrating on monitoring for and identifying any black market in unregistered pesticides. Where these activities are identified, assuming that they are occurring in a reasonably significant volume, Country D intends to make use of its strongest authorities to halt the practice and to impose severe sanctions, including criminal sanctions. These cases will also be widely publicized. The other focus for Country D is enforcement of the obligation of all importers and wholesalers to report annually on their imports and sales of registered pesticides. Because this is an important part of Country D's approach, violations of these reporting requirements will also be taken seriously, with appropriate compliance orders and penalty sanctions commensurate with the scope of violations, the extent of knowledge or culpability of the violator, and other factors. Second and subsequent cases of violations by the same entity will be treated more severely. It is not expected that these violations will warrant criminal sanctions, however, unless there is evidence of deliberate falsification or of on-going and egregious disregard for the law. Of course, if these entities are also engaged in the unlawful sale of unregistered pesticides, those violations could be subject to the most severe sanctions.

## **3.8 Evaluating programme success**

### *3.8.1 The importance of evaluation, measurement and accountability*

Respect for government is a critical component of any successful compliance and enforcement programme. Success in design and implementation depends on evaluation of results and continuous feedback to adjust and improve. The regulated community and the general public alike need to be able to see and understand what activities government is undertaking to achieve pesticide regulatory compliance, how those actions are being implemented, and what results they are achieving. Other participating nations and the world community will want to evaluate national enforcement of provisions implementing international conventions. Managers of national pesticide enforcement programmes need to work toward developing meaningful measures of programme success and regularly and publicly documenting results in terms of these measures. Programmes need to generate data and information for policy consideration and to review the rate of success of field programmes.

Measures can include activities (inspections conducted, cases initiated, penalties collected, persons trained), compliance measures (violations identified, tips and complaints received, compliance rates, compliance survey results) and environmental and public health measures (pesticide residues in food and drinking water, poison incidence reports.) No one measure, and not even a combination of these measures will tell the whole story, but they can give meaningful indications of results and a basis for comparison over time and across segments of the country or the regulated community.

Continuous programme review is also important to help evaluate the effect of approaches which may not work as originally anticipated. For example, the ban of a problem pesticide could lead to shifts to other, equally or more risky alternatives. The introduction of a labeling “improvement” such as warnings about toxicity, could create an unexpected perception that such products are more effective. Good programme measurement and accountability can make sound adjustments in situations like this.

### *3.8.2 Sample national implementation (Countries A,B,C,D)*

#### **Country A example:**

Country A decides to concentrate its initial efforts at measuring the impact of its compliance programmes by focusing on its disposal and water body contamination problems. Country A decides to conduct a modest monitoring programme of pesticide residues in ponds, lakes, and streams, and identifies a window of the pesticide use season where this monitoring would be most relevant. The plan is to conduct sampling over about a six to ten week period in each year, to evaluate the changes in residue levels from year to year, and to publish the results. Streams and water bodies that have been known to have experienced problems in the past and water bodies in areas of high pesticide use are targeted for this effort. Country A seeks scientific help from an international organization in order to design the monitoring so that it is cost effective and likely to provide scientifically useful information. This effort is supplemented by tracking of fish kill incidents and other indicators of water quality. Country A is also planning to track and account publicly for all of its investigatory efforts relating to the disposal problem and the nature of all enforcement actions taken. It is also working to develop some method of measuring whether and to what extent used pesticide containers are being properly handled.

#### **Country B example:**

Country B begins its evaluation and accountability processes by concentrating in two areas. Because coordination and joint activities with other parts of government are so important and because of the desire to encourage this process and make it more effective, Country B is tracking and reporting on all the various inter-agency activities that it conducts each year. In addition, because Country B has set itself a goal of returning violators to compliance and responding to violations within certain time frames (see Section 3.7.2), it is tracking and reporting on its success in meeting these time goals.

**Country C example:**

Country C is working with its provinces to develop a common set of measures and reporting and tracking systems that will be manageable and not unduly burdensome, but that will allow comparisons in performance not only from year to year but across the various provinces. The system needs to recognize the differences in activities and outcomes that are appropriate because of differing priorities and capacities, but to provide a means for describing the performance of the overall national compliance and enforcement programme.

**Country D example:**

Country D is developing measures of its activities relating to investigation and responses to the sale and use of unregistered pesticides. It is also attempting to track the volume or quantity of black market pesticides that it has identified and addressed in some way (e. g. stopped at the border; required to be returned or destroyed; seized).

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## Annex A

### Legal tools and instruments

- 1. Enforceable requirements**
  - achievable requirements
  - clear requirements
  - mandatory requirements
  - monitorable requirements
- 2. Defined illegal acts**
- 3. Monitoring authorities**
  - inspections and investigations
  - self-monitoring and reporting
- 4. Order and sanction authorities**
  - emergency authorities
  - compliance orders
  - civil and criminal sanctions
  - other

This appendix to the *Guidelines* goes into additional detail about the kinds of legal requirements that will enable, support effective pesticide enforcement programmes. They involve two basic types of legal provisions: those which impose duties upon manufacturers, sellers, handlers, users, transporters, disposers and any others involved in pesticide manufacturing, sale and use and those which establish authority for and set limits on government enforcement activities such as investigations and penalties. A.1 and A.2 of this Appendix relate to the first to these two categories; A.3 and A.4 to the second.

#### A.1 Clear, mandatory, monitorable requirements

Pesticides requirements are contained in legislation, in administrative regulations and orders, in licences or permits, or on mandatory, binding labeling. Wherever and however the requirements are described, they need to meet certain criteria in order to be enforceable and to facilitate compliance.

In the first instance, the requirements must be possible to achieve, practicable in the circumstances of those to whom they apply. While it can certainly be appropriate to impose requirements that are not easy to achieve and that involve costs and effort, there is no way to successfully enforce requirements that are plainly impractical. If requirements are too stringent, depend on technology that cannot be made available, or are effective too quickly without adequate time for the regulated community to take the steps to comply, the result can be a lack of respect for compliance with law and a lack of willingness on the part of government to enforce. It may appear that it is preferable to establish a very high standard in order to express the most desired outcome. However, it is more advisable to describe such high standards as goals, to establish them with a longer-term effective date, or to limit them

initially only to the larger commercial entities and to concentrate instead on requirements that can be achieved and enforced.

Secondly, the language must be clear, understandable, and unambiguous. This is often difficult to do when the information is highly technical and the requirements involve variation for different situations. It is important to be clear about who has the obligation (e.g., any person who uses the pesticide; any person who sells or offers for sale; persons include corporations and cooperatives, etc.) and about what activities are covered. For example, it can be very important to clearly define what constitutes a pesticide, what constitutes labeling (for example, does it include brochures that accompany the product?), what constitutes a sale or offering for sale (does it include donations or exchanges for services?), and all the other key concepts that govern which activities are covered. The drafters of each requirement should think through how they themselves could go about avoiding the requirement by taking advantage of loop-holes or unclear provisions. Then the requirement can be written to minimize the opportunities for evasion. Drafters should involve those with enforcement experience in the initial drafting of requirements. If there are exceptions or waivers of the requirement under certain circumstances, those circumstances also need to be narrowly and carefully defined. It is recommended that the obligation to show entitlement to an exception be put upon those claiming it.

Third, in order to be enforceable, the language must clearly impose a duty. A statement that a person (seller, user, etc.) *should* act in a certain way will generally be seen only as advice or encouragement. The failure to do so would not violate any duty. Words like *must*, *is required to*, and *mandatory are recommended*.

Fourth, it is important for both the regulated entity and for the government to be able to detect, determine, and measure whether there is compliance with the requirement. For example, limitations on the acceptable levels of pesticide residues in food, water sources, or soil must be accompanied by the existence of adequate tools and analytical methods to measure for such residues. If use of a pesticide is prohibited under certain conditions, like temperature or wind speed, those conditions should be clear and measurable. If only registered pesticides may be sold or used, it must be possible to precisely identify what pesticides are registered. The drafters of each requirement should ask themselves if they could figure out how to determine if they were themselves complying with the requirement as well as what evidence they would need to prove that someone is violating the requirement. These kinds of questions help to evaluate whether compliance can be readily determined. The involvement of both legal and technical enforcement personnel in the establishment of requirements or in the design of model licences or labels or the training of licence or label issuers is recommended. Sometimes requirements can include a duty to monitor for or document compliance. If so, the monitoring must be frequent enough and the documentation sufficiently complete to show on-going compliance rather than a one-time or occasional condition.

## **A.2 Defined illegal acts**

When the legislation, regulations, licences, orders, or labels are written to make it clear what acts and omissions are required, and it is at least possible to evaluate whether the requirements are met and perhaps self-monitoring or demonstration of compliance is required, it remains only to be sure that the failure to act in the required way constitutes a violation of law. Under some legal systems, there will be general provisions that make it either a civil or a criminal violation or both to violate any statute, regulation, etc. If these general provisions are clearly applicable to all of the various legal instruments used to impose duties relating to pesticides, nothing further may be required.

However, it is frequently necessary to specify in the applicable law whether and what violations of the pesticides requirements will be considered unlawful acts. For example, if the pesticide regulatory scheme relies heavily on the specific terms and conditions of each pesticide registration and each

label, then it is critically important to determine when and by whom it is unlawful to violate the terms of such licences and labels. Typically, the system would make it unlawful for licencees (registrants, permittees) to violate the terms of the licences and for users to violate the terms of the labels. Certain requirements and associated violations would be appropriate outside the licensing and labeling context, such as those relating to repackaging or transportation. The legal system should also designate violations of such requirements as unlawful acts. If only registered pesticides are intended to be lawful, the system must decide by whom and what activities are unlawful with unregistered pesticides. For example, it might be unlawful to sell or offer to sell or transport or even to purchase but not necessarily unlawful to use an unregistered pesticide. Or it might be unlawful for larger operations or facilities to use unregistered pesticides but not for small farmers or homeowners. Or only certain identified unregistered pesticides might be unlawful for use, although all unregistered pesticides would be unlawful to sell. (This is a very difficult area, especially if the definition of pesticide is very broad. Generally, government may wish to discourage but not necessarily make unlawful the “home remedy” pesticides.) In section A.4 below, the nature of sanctions and authorities which may be associated with various violations is discussed more fully.

### **A.3 Inspection, investigatory, and monitoring authorities**

Even where the resources to conduct inspections and to monitor are extremely limited, it can be very important to have a full range of legal authorities available for these activities. This can help maximize efficiency and planning and can be critically important in any major emergency or crisis. On the other hand, all of these kinds of authorities will need some kind of limits and due process protections to assure that they are not abused, and that both the regulated entities and the civil society will generally accept their use.

These authorities are generally of two types—authorities to support government inspections and other investigations and authorities to permit government to require monitoring or record-keeping by the regulated community.

#### *A.3.1 Authorities necessary for inspections and investigations*

In order to conduct inspections and other investigations, government officials will need the ability to gain access, enter and move about freely at facilities or operations where regulated activities occur, whether connected with the import or sale of pesticides, their storage or transport, or their use. Since all but the areas for use are usually commercial facilities, these provisions should be relatively easy to design and implement. However, because pesticides are used in an extremely wide variety of situations, including private homes and very small enterprises, more care may need to be taken in designing access requirements in certain use situations.

The authority to enter commercial facilities, including use facilities, should not require government to demonstrate that it has a basis to believe that violations are occurring but only that the facility is one where officials have a basis to believe that regulated activities are conducted. However, in the case of homes and similar situations, entry might reasonably be restricted to situations where there is probable cause to believe that violations are occurring. It may also be important to provide access to places where pesticides have been spilled or disposed or there is some other reason for government investigation even though the owner and operator of that place has not been involved in regulated activities.

Where practicable, inspection and investigation authority for pesticide laws should be consistent with similar authorities under other laws, such as environmental or health laws that may be applicable to the same or the same types of facilities. This promotes cross-training of inspectors, sharing of experience and techniques, and coordination of information about facilities.

The authority to enter, move about, and evaluate should also include authority to take samples, photographs, conduct interviews, and examine books and records. Authority should include the right to undertake a random system of testing of imports and product in wholesale and retail establishments. It would be appropriate to provide legal mechanisms to protect legitimate trade secret and confidential business information that is obtained in this way. If the investigation is likely to lead to a criminal sanction, other safeguards such as those that protect against unwilling self-incrimination might be appropriate, depending on the specific nature of the national criminal justice system.

One way to build confidence in the exercise of these authorities is to limit their use to persons who have government-issued inspector credentials and to take steps to assure the integrity of the system of issuing such credentials. If entry is denied or cooperation with inspectors is withheld, there will need to be ways for inspectors to obtain the aid of the courts, the police or some similar authority which will both obtain the necessary access and allow owners and operators of facilities to challenge such access. Another way to build confidence in government inspections and investigations is through general, usually government-wide laws and approaches to promote ethics and prevent conflicts of interests for government employees and to detect and punish bribery and other abuses.

Finally, it is important to encourage a sense of responsibility for identifying and reporting potential pesticides law violations throughout the government and civil society. Police and other government officials at the local or higher government levels and all citizens including those who work with or around pesticides can be helpful sources of information. It is a good idea to provide some training or awareness-raising to entities like police or those who work with pesticides. Police officials could be given authority for some extent of investigation of apparent violations, depending on their degree of training and the overall legal system and structure. Specific, identified points of contact to receive reports are recommended. In some instances, it may be appropriate to provide some kind of protection or anonymity assurance for individuals who may fear consequences from reporting of violations. These protections are sometimes called “whistle-blower” protections.

#### *A.3.2 Authority to require self-monitoring and recordkeeping.*

Either as part of licensing or through other provisions of legislation, government can implement requirements for the regulated community to develop a wide range of data or information that is relevant to compliance and to overall conditions. Such information can relate directly to compliance status, such as a requirement to sample and analyze a certain fraction or frequency of imported or marketed product to demonstrate that it complies with the specifications that apply to such export or sale. Alternatively, the information could relate to environmental conditions, such as requiring the periodic sampling of drinking water sources or of post-application residue levels in food or in interior treated spaces. These latter types of monitoring can help government identify areas where violations may be occurring or where new requirements might be appropriate. Both kinds of monitoring not only can help government determine how to respond, but also can serve to increase the attention and focus that regulated entities place on compliance and on stewardship.

In evaluating whether to require self-monitoring, record-keeping, and reporting, several factors should be considered: 1) practicality, costs, and burdens; 2) usefulness and intended purpose; 3) reliability and credibility; 4) ability of government to oversee and manage the information, including whether and how to make the information public. If the monitoring is to play a key role in the overall pesticide programme, it is important not only to make the desired monitoring a requirement, but to provide significant sanctions for any falsification or hiding of monitoring results. Self-reporting programmes require additional vigilance to assure their credibility and effectiveness.

Decisions will need to be made about the frequency and comprehensiveness of monitoring, whether all results should be reported to government, some portion of the results, or only those results that show violations or problems, whether and for how long records of the monitoring must be maintained, and whether and to what extent government can and should conduct independent verification of the

monitoring results. Even the issue of who should be required to conduct the monitoring can be complicated. Some kinds of monitoring can readily be imposed on, for example, each registrant/licensee or each importer/seller. Other types, say for periodic sampling of food residues, might not logically be required of any one company or entity. It might be possible to require all registrants to contribute to a single or unified monitoring programme in some instances. If this approach is taken, it should fit in some way with the existing fee structure and contain means for financial integrity.

To address reliability and credibility, governments may require certification of the results by company officials or independent entities, the use of government or independent laboratories, the use of good laboratory practices or other quality control techniques, the periodic splitting of samples for independent verification, and/or the submission of raw data. A requirement for independent oversight or observation, funded by the regulated community but genuinely independent and reporting to the government, might be appropriate for particularly complex or risky activities.

While all of these tools can make a big difference in supplementing scarce government investigation and monitoring activities, it is important to remember that they can be overly costly and burdensome to the regulated community and that the results may not have full credibility and reliability because of the perception or the reality that the regulated industry may have a conflict of interest when it comes to the results of such monitoring, especially if it could have the effect of proving violations of law or the need for further regulation. Therefore, these tools should be used in a measured, thoughtful way, as part of an overall approach to monitoring and investigations that includes a full range of tools and approaches.

#### **A.4 Legal authority to address emergencies, mandate compliance, impose monetary penalties, impose criminal sanctions**

In broad terms, governmental authority to respond to violations can be sorted in several ways. These authorities may be administrative or judicial. That is, they may be available for use directly by the administrative authorities or they may require involvement of the courts before they can be used. The authorities may be civil or criminal. The difference usually includes the fact that criminal sanctions carry more societal disapproval and open the violator to the risk of loss of personal liberty. There are advantages and disadvantages to all of these. A system generally works best when all are available and the government response can be appropriately tailored to the facts and circumstances of each situation. For purposes of this section, all of these types of authorities are discussed under one or more of the following categories: 1) emergency authorities; 2) compliance order authorities; 3) sanctions; and 4) other enforcement related authorities.

##### *A.4.1 Emergency Authorities*

In certain, usually rare situations, there is a need for an immediate and strong response to correct an imminent hazard, to stabilize and address the immediate impacts or immediately anticipated impacts of a major problem involving pesticides. These situations could involve harm that is already occurring or evidence that significant harm is about to occur or that conditions are such that it is reasonable to conclude that harm is likely. This can occur as the result of accident or deliberate acts, and may require action before an investigation into causation and fault has been completed. For situations like this, emergency response authorities can assure an orderly and effective governmental response. These authorities can take the form of administrative orders issued to owners, operators or other responsible persons to stabilize the situation, contain or clean up the immediately hazardous conditions, and provide necessary protections for persons on or off site who may be immediately affected. Alternatively, such orders could be obtained from a court and take the form of judicial orders, although there would be a need for expedited proceedings and a capacity for rapid action by

the courts. Because administrative orders may not be obeyed, it is usually necessary to have some recourse to the courts and the availability of some kind of expedited judicial proceedings in any event.

Related authorities could include the authority to seize pesticide products in the channels of commerce, in storage or transport and the authority to stop the sale and distribution of such products, where seizures or stoppage of sales is necessary to prevent an imminent hazard. Authority for government to step in and address the problem and ultimately obtain cost reimbursement from the responsible parties can also fit into this category.

Many of these types of emergency authorities may exist or be enacted into national law for situations that are not limited to pesticides. So long as pesticides-related emergencies are included in these broader emergency authorities, there would likely be no need for authorities specifically for pesticides.

#### *A.4.2 Compliance Order Authority*

Because government detection of a violation is not always sufficient to motivate the violator to comply, government needs the tools to require compliance. Even if the violator is willing to comply, it may not be possible to do so quickly and good enforcement practice would include orderly oversight of the schedule and intermediate steps to compliance. Compliance orders allow the enforcement authority to specify the steps necessary for the violator to come into compliance, establish reasonable but firm deadlines to do so, and create escalating consequences for those who do not obey such orders.

Compliance order authorities can include the authorities to order stoppage of production, importation or sales and the seizure or stabilization of goods in situations where those actions are directly related to on-going violations and are necessary and appropriate to prevent such violations. These kinds of actions, for example, are often suitable for unregistered pesticides.

Compliance orders may be either administrative or judicial (civil). They may be issued with the consent of the violator, in which the terms could be negotiated and agreed by both government and the violator. These are usually termed consent orders (or, if judicial, consent court decrees) and may include provisions for resolving disputes about compliance with the orders and for an agreed-upon penalty for failure to comply with any terms of the orders. Usually, the legal authority to issue compliance orders will include the authority to enter into consent orders, but it is wise to be sure that option is available under the applicable law. If consent cannot be obtained or if government does not believe it is appropriate, orders can be unilateral in nature. That is, they can be imposed directly on the violator without his consent.

Some violators will not only decline to consent to the terms of a compliance order but will choose to challenge the order rather than to obey it. Such challenges may be motivated by a lack of willingness to comply or by a sincere belief that the government action is not proper based on the facts or the law. For non-emergency judicial orders, the opportunity to challenge usually comes before the order is issued. The government administrative authority would file the matter with the court, asking for the order, and the court would hear from both parties before determining whether to issue the order. If a violator is expected to forcefully challenge a compliance order, going to court can often be the most direct route to obtaining compliance, since once a judicial order is issued, the full power of the court is available to assure compliance with the order.

However, the administrative authority usually can more quickly and easily issue a unilateral administrative compliance order and often the use of the administrative procedure will obtain compliance. When the violator nevertheless wishes to challenge the administrative order rather than obey it, two types of approaches could be used. Under one approach, there could be an administrative procedure to consider such challenges, with a final administrative determination following the appeal.

Alternatively, the administrative authority could be required to go to the courts to obtain a court order for compliance with any administrative orders that do not obtain compliance on their own. Both approaches have advantages and disadvantages. An administrative appeal process may be more efficient, quicker, and lower cost for all involved. On the other hand, this very ease could have the effect of encouraging challenges to such orders. Further, if the violator does not prevail in the administrative appeal and persists in refusing to comply, an ultimate recourse to the courts would be necessary in any event.

Fortunately, experience has shown that administrative compliance orders can be effective in a large percentage of cases. For those relatively few situations where they are not, it is important that there be a clear, understandable, and effective procedure for hearing the challenges by the alleged violator and for obtaining compliance if the challenges are not successful.

Finally, compliance requirements can be imposed as a result of criminal proceedings. In most, if not all, legal systems, criminal sanctions are imposed as a result of some type of judicial process. At some point in the process, including a trial if the accused chooses to exercise that right, the matter of a proper sentence will arise. As discussed below in section A.4.3.2, criminal sanctions can include monetary fines and/or loss of personal liberties. In addition to such sanctions, judges can impose conditions on the criminal sentence which could include compliance terms as well as other types of conditions.

#### *A.4.3 Sanctions*

Sanctions are the means of assuring that there are adverse consequences to those who choose to wait until detected before coming into compliance. Sanctions can also serve to assure economic fairness by removing the competitive advantage gained by those who violate rather than bear the costs of compliance. Generally, sanctions take the form of civil monetary penalties, either administrative or judicial, and of various criminal sanctions.

##### A.4.3.1 Civil Monetary Penalties (Administrative and Judicial)

Before considering monetary sanctions, in some situations, a decision may be made that no immediate sanction is appropriate in a particular case, but that it is important to document the violation and to lay the groundwork for a more severe response if there are future violations. Under these situations, the preferred action could be a warning notice or letter or the imposition of a monetary penalty that is then suspended or forgiven, perhaps only so long as there are not further violations. For this kind of response, it to have administrative authorities, as such actions would not warrant the burdens and costs of the judicial system.

In establishing the authority to issue monetary penalties, choices must be made about where the authority is designated (administrative or judicial), the amounts and types of such penalties, and the procedures for challenges or appeals.

It is possible, and recommended where practical, to design a system with both administrative and judicial avenues for monetary penalties. In some systems, the amount which can be imposed administratively is set lower than for judicial actions. If this design is adopted, it is important to set the administrative limit high enough to provide meaningful use of the administrative tool.

The amount authorized for penalties is always a complicated question. As a practical matter, it is almost impossible to establish in legislation a precise penalty amount that fits each of the wide range of potential violations. Therefore, it is customary for the legislation to authorize up to a set amount for each violation or for each day of violation. It is understood that this is the maximum potential penalty, intended for the most severe and compelling situation. However, this assumption will work best if the maximum is set at a significantly higher level than will be warranted in many situations, and it will be

important for all concerned to understand this assumption. The establishment of the maximum penalty level should also take into account whether it is sufficient to recover the economic benefits from non-compliance where appropriate. The establishment of a specific maximum penalty can be complicated where currencies are unstable and inflation occurs at a rapid rate or in highly unpredictable ways. It is recommended to build in a process for the maximum to be automatically or at least easily adjusted in the event of inflation.

Because of the wide discretion that would have to be exercised where the maximum potential penalty is considerably greater than would fit many specific cases, it is a good idea for the enforcement authority to be consistent and transparent in its approach to penalties. A schedule of typical penalties could be published periodically, or all penalty cases could be made public in some systematic way. A set of factors which are considered in setting penalties could be provided, along with other aspects of penalty policies and approaches. One or more of these approaches to transparency should be adopted.

Where there is a need for a compliance order, it will usually be logical and efficient to seek penalties at the same time and in the same manner as issuing the compliance order. If there is consent to the order, a process for negotiating and consenting to penalties would also be recommended. If the order is issued administratively, that would likely be the best option for companion penalties. Similarly, if a court is asked to order compliance, it would likely be best to seek a court order for penalties at the same time. Opportunities for this kind of coordination should be factored into the design of compliance order and penalty authorities.

If there is no compliance order to be issued, perhaps because the violator complied before one was issued or the violator is no longer subject to the requirements, then the penalty action would be negotiated as a consent matter or brought unilaterally either through administrative or judicial authorities. As with compliance orders, there would need to be a means for challenges or appeals and a process (usually judicial) for ultimately enforcing the payment of the penalties after the challenge and appeal process is over, in the event of a refusal to pay.

#### A.4.3.2 Criminal Sanctions

The nature, role, and use of criminal sanctions can vary considerably across national legal systems. In some systems with extensive civil penalty authority, criminal sanctions are reserved for the most severe and egregious cases and require the government to bear a very high burden of proof. However, in systems with limited or no judicial or administrative penalty authority, the criminal law system is also used for much less serious violations across a large segment of matters regulated in the society. Even routine traffic offenses may go through the criminal law system. Of course, both the degree of societal stigma and the severity of the criminal sanctions vary much more widely in the kind of legal system in which the criminal law covers a much broader range of violations and violators.

Therefore, the manner in which the criminal law is used to enforce pesticide requirements is likely to depend heavily on the overall national approach to the use of the criminal code and criminal procedures. Regardless of those factors, however, the basic sanctions available under the criminal law are monetary (fines) and various forms of loss of liberty, up to and including imprisonment. Lesser forms of loss of liberty can include mandatory public service, “house arrest”, constraints on travel and movement, and other personal constraints. Since corporations usually cannot perform these liberty-related sanctions, criminal penalties upon corporations are usually limited to fines, although individual corporate officers might be held accountable for violations under certain facts and circumstances.

The authority for criminal monetary sanctions should consider the same factors as described in Section A.4.3.1 for civil penalty provisions, although it might be appropriate to establish the option for higher or more severe amounts of criminal fines under certain extreme or aggravated circumstances. In any event, the approach for criminal fines should not be less rigorous than for civil

penalties, including consideration of factors like economic gains from violative behavior and the impact of inflation on maximum penalty amounts.

#### *A.4.4. Other Enforcement Related Authorities*

Certain other governmental actions can have the effect of achieving compliance and/or punishing and deterring violators. These include the barring of violators from participation in government programmes or contracting with the government, the revocation of licences or permits, and the shutting down of facilities. These provisions, too, could be administrative or judicial and would need to have mechanisms for appeals and challenges and for ultimate recourse to the courts.

## Annex B

### Developing Enforcement Capacity—Institutions

This section of the *Guidelines* goes into additional detail about the kinds of institutions, infrastructure, technical resources, and expertise that will help create successful pesticide compliance and enforcement programmes.

#### Institutions, Infrastructure, Resources and Expertise

- **Agenc(ies)**
- **Inspectors (Who they are and Duties)**
- **Equipment/Laboratories**
- **Scientific, legal, administrative expertise**
- **Independence/Professionalism/Integrity**
- **Coordination**

#### B.1 Agenc(ies)

The primary pesticides compliance and enforcement programme will likely be located within some larger structure, taking into account the major factors discussed in Section 3.1.

Wherever the “primary” home of the pesticide enforcement programme, that section makes it clear that there is certain to be significant need for coordination and collaboration with other entities within the government.

There are options for how many of the functions and types of skills/expertise to co-locate within the primary enforcement programme. For example, should lawyers be included in the programme or should lawyers in the justice ministry or elsewhere (e. g. public prosecutors, privately contracted attorneys) provide necessary legal support? Should the enforcement programme have some level of independent laboratory capacity or should it rely on another organization’s laboratory? What about specialized investigatory skills and equipment: in-house or externally obtained? Should compliance assistance and compliance promotion activities be combined with or separated from compliance monitoring, inspections and responses to violations? At the outset of establishment of compliance and enforcement programmes, there may be only one practical answer to these questions—only the most basic skills and expertise, used as broadly as possible, will be initially available. However, some degree of planning for how to handle these questions will help inform early decisions about the first steps in each of these areas. Some recommendations about answers to these questions are discussed below in specific sections on each topic.

When it becomes possible to address these questions more meaningfully, designers will want to consider the advantages of establishing in one place all the relevant specialized equipment and personnel dedicated exclusively to the pesticide enforcement functions with direct reporting accountability and increased control over prioritization of work within a single organization. Those advantages can then be balanced against the potential to take advantage of the features of larger pools of specialists or tools from outside the agency and to create cross-organizational checks and balances through the involvement of other, specialized organizations, which may be longer-established structures. It may also be difficult in a single, small primary programme to recruit and supervise a range of special disciplines, like attorneys or laboratory chemists and to properly maintain specialized equipment that may only require limited use.

## **B.2 Inspectors**

In many ways, inspectors form the heart of any enforcement programme. They represent the face of the Agency to the regulated community and the eyes and ears of the programme in the field. Their knowledge and expertise provide much of the programme's understanding of the regulated community, and the results of their inspections help both to describe the overall state of compliance with requirements and to serve as the first step in correcting violations and in deterring others from violating.

### *B.2.1 Who inspectors are*

The issue of who should serve as inspectors involves several questions. Should the inspectors be permanent civil servants or contracted from the private sector? What kind of background and skills should be identified when selecting inspectors? Should inspectors specialize in a portion of the requirements (e.g. sales, commercial building application) or cover a broader range of the requirements? Should inspectors be assigned to particular geographic areas or move around throughout the relevant areas? For each of these questions, there are recommendations for consideration in this section.

While, in general, civil servants may demonstrate more commitment to the mission and purpose of the enforcement programme, may develop longer careers with greater long-term training and expertise, and may be more easily held accountable to standards of ethics and fairness, it may not always be practical to staff all inspection activities with permanent civil servants. Private contracted inspection services can be particularly suited to a short-term focused priority activity, for the period of transition while more permanent employees are selected and trained, for more routine aspects of inspections, to address a backlog, or where there has been some loss of confidence in the civil service. If contracted services are used, it is critical to assure that they are qualified, independent of the regulated industries or any other special interest, capable of maintaining appropriate confidentiality and capable of demonstrating integrity and fairness. Inherently governmental functions like the issuance of orders and the use of sanctions should always be conducted under the supervision and authority of government personnel. Contract inspectors should be used primarily as a stop-gap measure and a career public servant inspector corps should be developed where possible.

Much inspector training will be on-the-job or specific to the requirements and activities that are the subject of inspections. Therefore, there are no educational or experience characteristics that describe the ideal inspector. Inspectors should be organized, clear thinkers, observant, capable of understanding the sometimes scientifically and legally complex issues, capable of careful and precise evaluation of documents and physical conditions, flexible, fair-minded and honest. They should be able to understand and fully accept the core principles of compliance and enforcement programmes as well as the specific requirements of the pesticide regulatory system and the nature of both inspection

activities and the activities, like compliance orders or sanctions, which may rely on the results of inspections.

Specialization of inspectors can help to enhance the depth of expertise and can be particularly important for extremely complex aspects of the regulatory system. However, specialization can also mean the inspector does not fully understand how particular requirements fit within a larger context and could lead to repetitiveness and boredom. It makes best sense for matters like import/export requirements, where the inspections may be conducted by customs officials or for other requirements where the inspectors may also focus on related, non-pesticide specific requirements like work-place health and safety provisions or transportation requirements. Otherwise, it is recommended that inspectors be trained to cover a relatively broad scope of requirements.

Whether inspectors should concentrate by geography or industry segment also raises the delicate question of the nature of on-going relationships with the regulated community. Because the inspector spends much of his or her time with representatives of the regulated community and develops a thorough understanding of the nature and difficulties of their activities and operations, it is natural that a certain empathy would develop. If appropriately handled, this is a good thing, as it assures that government has a sound understanding of the challenges facing the regulated community. On the other hand, as these personal relationships become closer and endure over longer periods, there is a risk of lack of independence and objectivity in the exercise of the inspector's professional duty. There are a number of ways to address this concern, but one approach that can help is to limit the extent to which inspectors are involved only with one geographic or industry sector. Some governments systematically rotate inspectors for this reason, and where practical, that solution is recommended.

### *B.2.2 Inspectors' Duties*

In determining the scope of inspectors' duties, an important question is whether to assign primarily to inspectors the role of follow-up enforcement response actions when violations are found. At the one extreme, inspectors could simply gather information and provide it to others, without even conveying opinions to the inspected facility about whether there appear to be violations. At the other extreme, inspectors could be empowered to choose the enforcement response (from warning letter to large monetary penalties) and to take the steps to impose that response, whether through negotiation or unilaterally. Something between these extremes is recommended, with inspectors providing some feedback to the regulated entity at the time of the inspection, but involving others in the decision-making about what follow-up response is appropriate and working with others, as either the leader or in a supporting role, to undertake the actual follow-up enforcement action.

Inspectors' duties consist primarily of pre-inspection, on-site, and post-inspection elements. Some of these elements, especially the pre- and post- activities may involve others. Pre-inspection activities include identifying the places or entities to inspect, determining whether the inspection should be announced or unannounced, gathering relevant background information and documentation, obtaining necessary safety and investigatory equipment, and arranging travel and other logistics. On-site activities include gaining entry (which, if refused, could require use of courts or other authorities); proper use of safety equipment; handling and use of investigatory tools like photographic equipment, sampling equipment and samples; reviewing and obtaining copies of records; interviewing of personnel; and providing appropriate information and feedback. Inspectors should be trained and competent to sample products for verification of content formulation.

Post-inspection activities include the preparation of reports, the submission of information for any relevant information management systems, the preservation of evidence and information, the analysis of the significance of the information obtained, the initial determination of what violations were identified, and the development of a strategy to respond to violations. Inspection reports should also be subject to internal verification procedures as a check and balance. Finally, inspectors are likely to be involved in any contested administrative or judicial proceedings to impose compliance orders or

sanctions. Because the inspection will be the source of much of the evidence upon which actions are based, inspectors are likely to be witnesses to the factual aspects of any dispute. Inspectors may also be appropriate to serve as witnesses for their overall expertise regarding the requirements and the means for complying with them. If negotiations are conducted with the regulated entity, inspectors may be included in the negotiation process, both for their knowledge of the particular violations and for their general expertise. If there is publication of information, involvement with the press, or even conduct of special presentations at trade conferences or other meetings, inspectors could also be called upon to play a role.

### **B.3 Equipment/laboratories/etc**

While complicated and expensive equipment can certainly be very useful for inspection and other investigative and enforcement activities, it is not necessary. Appropriate safety equipment is necessary for certain activities, but it is often possible to avoid those activities and still have a useful and workable enforcement programme. Regulated entities or private contractors can be used to conduct sampling and analysis in many instances, provided care is taken to avoid conflicts of interest. So, it is perfectly appropriate to concentrate first on very basic needs like transportation to and from inspection sites, simple photographic and records-management equipment like logbooks and portable files, pocket calculators, basic communications equipment like cellular telephones or phone cards, and basic safety equipment like safety glasses, sturdy shoes, simple headgear and clothing that covers arms and legs, work gloves, hand and face washing materials, and a first aid kit. The safety of personnel must be paramount, but beyond that the key concerns are mobility and communications, before, during, and after field activities.

As enforcement programmes grow and mature, additional capabilities and related equipment can be added. Portable computers, equipment for convenient copying of written materials, means for recording interviews, and basic sampling and sample transport equipment would probably be included as capacity expands. While most pesticide enforcement programmes will not have to have their own ability to analyze samples, access to reliable, independent laboratories will be important and may be difficult to obtain. Other state sector facilities have their own clear mandates and privately funded facilities may provide very costly or inadequately verified analyses. Report timeliness can also be a problem as can the form or modality of results. For these reasons, pesticide programmes with adequate resources should move toward in-house or dedicated outside laboratory capacity.

As inspection activities warrant, advanced safety equipment like respirators, hard hats and face shields, rubber or neoprene boots and aprons, and the like should be added. In the absence of such equipment, activities which require it should not be undertaken.

Inspectors and others should be well trained in the use of all equipment (including transport vehicles) and in first aid and other safety and investigatory procedures. It is not wise to introduce equipment without training and experience in its use. Similarly, equipment should be maintained and stored in a manner that assures its continued effectiveness. Samples should be handled in a manner that assures both scientific validity and credibility in the event of court or other contested proceedings. Records should be handled to assure appropriate confidentiality, reliability and credibility that they have not been altered and are complete and authentic. Training should cover all these considerations, as well as understanding and familiarity with field conditions, including both safety and compliance related factors.

Information resources are equally important. Libraries, on-line or internet based resources, and good information management systems are all part of the equipment of effective enforcement programmes. Attorneys will need access to legal research resources and scientists will need access to scientific libraries, analytical methods, and related information.

## **B.4 Scientific/legal/administrative expertise**

While field personnel, primarily inspectors, form the core of the staffing of enforcement programmes, there are a number of other important professional backgrounds that can be very important. For the more complex issues that may arise, such as those relating to the integrity of formulations or the presence of measured residues in environmental media like air, food or water, chemists or other scientists can be important. For evaluations of complex data on sales and marketing of pesticides, accountants or financial experts can be useful. Over time, it will become more clear what kinds of specialized scientific or similar expertise are needed with enough frequency to consider including that background among those staffing the Agency and what kinds of expertise may be needed on an occasional basis and better obtained through coordination with other government agencies or through contracting with the private sector. In developing countries especially coordination may be limited by each of computer or communication equipment and other factors. Attention to improving hardware and software for internal and external coordination is strongly recommended.

Because the regulatory requirements are imposed through legal instruments like laws, regulations, licences, and binding labels and because both administrative and judicial enforcement actions involve the use of legal authorities and may lead to contested proceedings, there is a need for access to lawyers and legal expertise. Some enforcement agencies include attorneys as part of the permanent staffing. In these situations, the attorneys are available to help with the development of enforceable requirements, to advise about approaches and models for compliance orders and penalty actions, to develop and help implement individual orders or penalty cases, and to represent the Agency in the event of an appeal or contested proceeding relating to the action. The assistance of lawyers can also be important if it is necessary to obtain access to a facility in order to conduct an inspection. Lawyers can advise about procedures for handling of potential evidence to assure that it can be used in court, and can help to prepare inspectors and others who may need to appear in administrative hearings or in court.

Some enforcement programmes rely on attorneys from other organizations, such as the Justice Ministry, or in the private sector. (In the case of the use of private sector attorneys, these attorneys usually only represent the government, in order to avoid a conflict of interest. They may, however, represent several government agencies). This approach allows the enforcement agency to have access to a greater or lesser supply of legal assistance as the need for it varies, and to take advantage of the hiring and management of attorneys by other organizations. However, it may be likely to lead to less use of the skills of attorneys and such attorneys may not be adequately familiar with the particular issues relating to pesticide regulation and enforcement. Of course, the approaches can be combined, with some attorneys within the enforcement programme agency and others located elsewhere. This combined approach is recommended as an initial approach to attorney staffing, as it provides some in-house capacity while also assuring access to a larger pool of legal resources in situations where that becomes necessary.

There is often some concern that over-reliance on attorneys will lead to unnecessarily adversarial or overly legalistic approaches. On the other hand, inadequate attention to legal considerations can lead both to violations of individual rights and unsuccessful enforcement actions. The key is to train and manage the participation of attorneys so that it is constructive, adds value, and promotes the overall success of the compliance and enforcement programme.

Some other skills can also be very important. Understanding and expertise on interacting successfully with the public, with stakeholders and with the press can be very valuable, for example. Training in public communication is recommended.

Finally, but by no means less importantly, the administrative function of the enforcement programme needs able and professional leadership. Sound and workable information management systems and logistic support are fundamental. Computer skills, for example, can enhance the opportunities for electronic communications and information management.

Newly emerging enforcement programmes will find it difficult to develop the desirable range of professional skills and backgrounds. Creative approaches to involve such expertise from other governmental organizations or, where appropriate, private sector sources, additional training for existing personnel, use of task forces and networks, all are recommended.

## **B.5 Independence/Professionalism/Integrity**

While all government functions should be done with professionalism and integrity and should be independent of improper influence, the enforcement function of government is particularly sensitive because it is both the tool by which government assures that its laws are meaningful and implemented and a means by which government can take potentially harsh and punitive actions against persons and entities. As discussed throughout these *Guidelines*, the legal system can and should adopt processes that protect the rights of potentially affected individuals and that enhance the ethical standards of government representatives.

While enforcement programmes necessarily and properly operate within the political system of the relevant national or sub-national governments and are accountable to the processes by which national policy is developed and implemented, it is also important that enforcement activities be seen as having longer term continuity and consistency. In general, the basic principles of compliance and enforcement should be sustained through changes of government leadership. To achieve this, enforcement programmes need a measure of independence and public accountability that assures the public of the continued viability of such programmes and that contributes to a culture of compliance with the rule of law.

If enforcement personnel are adequately trained, adequately compensated, have reasonable job security, can be replaced for non-performance or for malfeasance in office, and are subject to public accountability through governmental openness and transparency, then the overall national enforcement programme is likely to enjoy a high level of credibility, which will, in turn contribute to its effectiveness.

## **B.6 Coordination**

Probably no topic is mentioned more often in these *Guidelines* than coordination with and among various governmental and non-governmental entities that are important to successful compliance and enforcement programmes. It is fitting, then, to conclude this Appendix with a few additional specifics about successful coordination.

Coordination is important at multiple levels. Senior level officials need to know and understand each other's roles and to build leadership support for continuous and effective interaction between their respective organizations. Working level personnel need to know and be free to interact with their counterparts in other organizations on a continuous and effective basis, without unnecessary bureaucracy or complicated protocols. Helpful structured processes include periodic meetings, scheduled and unscheduled conference telephone calls, joint activities, standing committees, networks, task forces, newsletters, contact lists. Short or longer-term personnel exchanges between coordinating organizations can be very helpful, as can mutual training exercises.